Human Embryos, Patents and Global Trade

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Human Embryos, Patents and Global Trade: Assessing the Scope and Contents of the TRIPS Morality Exception

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Abstract
Can a World Trade Organization (WTO) Member exclude an invention from patentability on the grounds of *ordre public* or morality whilst at the same time permitting the sale and distribution of the invention within its territory? This is a question raised by recent developments in Europe, where moral restrictions have been placed on the patentability of 'uses of human embryos', yet human embryonic stem cell (hESC) research, which involves the destruction of human embryos, is permitted and encouraged within numerous EU Member States, and indeed, also funded through the central EU science budget. This chapter assesses whether such an incoherent regulatory landscape would survive WTO scrutiny. The chapter argues that in general, if a WTO Member has not attempted to ban the commercial exploitation of a certain invention within its borders, measures prohibiting the patenting of that invention on moral grounds would likely be viewed as constituting an unjustified restriction on international trade. More concretely, it is suggested that the WTO Member would be found to be in violation of its obligation under the TRIPS Agreement to make patents available without 'discrimination' as to the field of technology.

Keywords
TRIPS Agreement, patent, morality, moral exception, human embryo, international trade, WTO.

Introduction[1]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a multilateral agreement on intellectual property that was concluded in 1994 as part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).[2] According to its preamble, the TRIPS Agreement reflects the desire amongst WTO Members:

> [T]o reduce distortions and impediments to international trade, and … to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.

In order to achieve its stated goal of enhanced trade liberalisation, TRIPS imposes an obligation on all WTO Members[3] to provide minimum standards of intellectual property (IP) protection. Members must make available and enforce a range of intellectual property rights (IPRs), including copyright, patents, trademarks, industrial designs and geographical indications, without discrimination as to the nationality of the right holder. TRIPS is administered by the WTO, and disputes between WTO Members concerning the interpretation of TRIPS and its implementation in national laws are subject to the WTO dispute settlement system.[4]

Article 27.1 of the TRIPS Agreement establishes a basic requirement on WTO Members to make patents 'available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'. It further adds that 'patents shall be available and patent rights enjoyable without discrimination as to the … field of technology'. Article 27.2 of TRIPS, however, provides a limited exception to Article 27.1 which states that:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Both the wording and the underlying policy objectives of the TRIPS morality exception are somewhat ambiguous and obscure. Unsurprisingly, this has led to a lack of clarity and agreement over the precise conditions under which a WTO Member may rely on an Article 27.2 defence to justify derogation from its core obligations under Article 27.1. A low-intensity academic debate on this question has seen opinion split broadly into four views.

One group of commentators suggests that a WTO Member must first prohibit the commercial exploitation of an invention within its territory before it is entitled to exclude the invention from patentability on moral grounds.[5] A second group takes the diametrically

[1] The author would like to thank Dr James Harrison at the School of Law, University of Edinburgh, for helpful guidance and advice on this paper. Any mistakes or omissions are the sole responsibility of the author.

[2] For a detailed discussion see D Gervais *The TRIPS Agreement: Drafting History and Analysis*, 2nd edn (Sweet & Maxwell 2003). For an overview of the structure of the WTO Agreements and all the WTO legal texts including the TRIPS Agreement, see:
<http://www.wto.org/english/docs_e/legal_e/legal_e.htm>.

[3] As of May 2009, 153 in total.

[4] For a summary of the Dispute Settlement System, see:
<http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm>.

[5] P Van Den Bossche *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, 2nd edn (Cambridge University Press 2008) 785.

opposed view that the wording of Article 27.2 only requires the decision of a competent authority (such as a legislative body or perhaps an individual patent examiner) that a ban is *necessary* to protect morality, but does not impose any legal requirement for the Member to also take positive steps to prohibit the actual commercial exploitation of the invention.[6] According to the third view, meanwhile, the interpretation of Article 27.2 would be influenced by the 'morality jurisprudence' of the European Patent Office (EPO) that has been built up in relation to Article 53(a) of the European Patent Convention (EPC).[7] Finally, the fourth group suggests that when reviewing a WTO Member's decision to exclude inventions from patentability in order to protect *ordre public* or morality, a WTO panel or the Appellate Body would apply the 'necessity test' used to scrutinise measures adopted under the 'exceptions clauses' found in other WTO Agreements; namely Article XX of GATT and also Article XIV of the General Agreement on Trade in Services (GATS).[8]

Until recently, the interpretation of Article 27.2 has been a question of little practical importance and of only marginal academic interest. The provision has lain entirely dormant, as there have been no disputes in which a WTO panel or the Appellate Body has been called upon to clarify its scope and contents. However, the recent 'moral turn' in European biotechnology patent law that has resulted in moral limitations being placed on the patentability of hESC-related technology, yet without accompanying prohibitions on the production and sale of such inventions throughout the EU, has arguably increased the significance of Article 27.2 for international trade and heightened the need for a clearer sense of the contours of this rule.[9]

Conceivably, Article 27.2 could be used to attempt to justify arbitrary and irrational decisions regarding the patentability of inventions. It could also be used more cynically to mask protectionism and 'free-riding'. A WTO Member could, for instance, reject the patentability of certain biotechnological or pharmaceutical inventions developed in other countries under the pretext of moral objections, but then copy and manufacture the invention itself or allow its domestic manufacturers to do so. This would disadvantage foreign companies who would otherwise enjoy patent protection and market exclusivity.[10] It can therefore be surmised that without any kind of WTO scrutiny over measures adopted under Article 27.2, the TRIPS morality provision could well become the exception that swallows the rule of Article 27.1.

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[6] D Leskien and M Flitner 'Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System', (1997) International Plant Genetic Resources Institute, Issues in Genetic Resources No. 6, Rome. Available at: <http://www.bioversityinternational.org/publications/Pdf/497.pdf>.

[7] Suggested in N Pires de Carvalho *The TRIPS Regime of Patent Rights*, (Kluwer Law International 2002) 170–171.

[8] D Gervais *The TRIPS Agreement: Drafting History and Analysis*, 223. Also discussed in C Henckels 'The Ostensible Flexibilities in TRIPS: Can Essential Pharmaceuticals Be Excluded from Patentability in Public Health Crises?' (2006) 32 Monash U L Rev 335-356 at 348–351.

[9] A detailed background discussion of the patentability of hESC-related inventions in Europe and the regulatory regimes for hESC research in individual EU countries is beyond the scope of this paper. Readers are referred to the other chapters in this volume, and also: A Plomer et al. 'Stem Cell Patents: European Law and Ethics', (2006) European Commission, available at: <http://www.nottingham.ac.uk/law/StemCellProject/project.report.pdf>; A Plomer, K S Taymor and C Thomas Scott 'Challenges to Human Embryonic Stem Cell Patents' (2008) 2 Cell Stem Cell 13–17; R Fitt 'New Guidance on the Patentability of Embryonic Stem Cell Patents in Europe' (2009) 27 Nature Biotechnology 318–319; 'EU to Fund Embryo Cell Research' BBC News (24 July 2006) available at <http://news.bbc.co.uk/1/hi/world/europe/5209106.stm>; A Elstner et al. 'The Changing Landscape of European and International Regulation on Embryonic Stem Cell Research' (2009) 2 Stem Cell Research 101–107.

[10] A discussion of the policy arguments for and against the use of Article 27.2 in this manner from the perspectives of international development and the right to health is outside the scope of this paper. See generally 'Integrating Intellectual Property Rights and Development Policy' Commission on Intellectual Property Rights (London 2002). Available at: <http://www.iprcommission.org/graphic/documents/final_report.htm>.

This chapter is divided into two parts. Part A presents the divergent academic views on the scope and contents of Article 27.2 of TRIPS and also briefly reviews the jurisprudence on the interpretation of morality-based exceptions in WTO Agreements. Part B sets out the principles of treaty interpretation that would be applied to Article 27.2 and then suggests the interpretative approach that a WTO panel or the Appellate Body might adopt when attempting to flesh out the meaning of this vaguely worded provision.

A: Divergent views on the TRIPS morality exception

Academic opinion is divided over the question of how Article 27.2 should be interpreted. A survey of the literature reveals four distinct views:

(1) The 'necessity of a ban on commercial exploitation' view

Can the TRIPS Article 27.2 exception be applied while at the same time allowing the distribution or sale of the invention, or is there is a need for an actual ban on the 'commercial exploitation' of the invention itself? According to the first view, an effective ban must be in place in order to justify invoking the exception. Van Den Bossche, for example, asserts that:

> The link between the use of the exception and the prevention of commercial exploitation of the invention in the territory of the Member aims to ensure that this exception is not used to deny patent protection to an invention on public order or morality grounds, while the invention itself is in fact commercially exploited in the Member.[11]

This view has much to commend it. The test it sets out is simple and straightforward; requiring merely a reasonable degree of consistency between the standards of *ordre public* or morality expressed within a WTO Member's patent laws and those expressed within the Member's domestic regulations governing the sale and distribution of particular inventions. This approach also coheres with a key principle running through the entire WTO compact, i.e. that deviations from WTO obligations should not be made lightly.[12]

(2) The 'prohibition of commercial exploitation is not necessary' view

Other commentators disagree with the above position. On its wording, Article 27.2 only points to the 'necessity' of such a ban, and does not state in definitive terms that a prohibition *must* be in place.[13] Leskien and Flitner therefore suggest a second view, arguing that TRIPS:

> [D]oes not require an actual ban on the commercialization as a condition for exclusions; only the necessity to prevent—by whatever means—the commercial exploitation of the invention. Yet the member state would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited.[14]

Leskien and Flitner also assert that the inclusion of the final phrase in Article 27.2 ('provided that such exclusion is not made merely because the exploitation is prohibited by domestic

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[11] P Van Den Bossche *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, 785.
[12] Appellate Body Report, *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services (US—Gambling)*, WT/DS285/AB/R (adopted 20 April 2005), para. 308.
[13] CM Correa *Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2007), 291.
[14] D Leskien and M Flitner 'Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System' 15.

law') lends additional weight to the view that an effective ban is not a necessary condition for the denial of patents:

> This qualification makes clear that the assessment of whether or not the commercialization of a particular invention is necessary in order to protect *ordre public* or morality does not depend on any national laws. Conversely and by the same token, a particular invention may be excluded from patentability although its commercialization is (still) permitted under a member state's national laws.[15]

Further support for this overall argument lies in the fact that if the drafters of TRIPS had intended a ban on the commercial exploitation of the invention to be a precondition for reliance on Article 27.2, different language could have been used to reflect that policy objective. As the framers of Article 27.2 chose deliberately not to use a format such as: 'Members may exclude from patentability, the commercial exploitation of which *has been prevented* in their territory in order to protect ordre public or morality…', it can be suggested that a ban on the commercial exploitation of the invention was intended, at best, to be merely one way in which a WTO Member could demonstrate the necessity of the prevention of the commercial exploitation of the invention, but that a ban is by no means required by a strict construction of the text of Article 27.2 itself.

(3) The 'EPO morality jurisprudence' view

A third view is to suggest that because the TRIPS Agreement borrowed the term '*ordre public* or morality' from the EPC, the interpretation of Article 27.2 may be influenced by the case law of the EPO in relation to how this phrase, found in Article 53(a) EPC, has been understood.[16] In general, the EPO has applied Article 53(a) in a restrictive manner. Of the numerous biotechnology patent applications in which the morality of the invention has been questioned,[17] only one patent application—for a genetically engineered hairless mouse that could be used to assist research into treatments for baldness[18]—has been held to contravene Article 53(a) EPC. The exact legal tests that have been used by the EPO have varied from case to case, with references to, *inter alia*; a weighing and balancing of the harms and benefits of the commercial exploitation of the invention,[19] the 'standards of morality inherent in European society and civilisation'[20] and 'public abhorrence'.[21] Importantly, none of these tests require the exclusion of patentability to be tied to a ban on the commercial exploitation of the invention.

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[15] Ibid, 15–16.

[16] Suggested in N Pires de Carvalho *The TRIPS Regime of Patent Rights*, 170–171. Article 53(a) EPC 2000 states that: 'European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States'. This is a change in wording from Article 53(a) EPC 1973, which provides that: "European patents shall not be granted in respect of: (a) inventions the publication *or exploitation* of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States" (emphasis added).

[17] For an overview and commentary, see A Warren-Jones 'Vital Parameters for Patent Morality: A Question of Form' (2007) 2(12) JIPLP 832–846.

[18] Upjohn's Application (Hairless Mouse) [1991] EP 89 913 146.0 (unreported). The Examining Division held that the invention violated Article 53(a) EPC on the grounds that '[h]air growth and wool production are not connected with any kind of serious threat to human being'.

[19] *Harvard/Oncomouse* [1990] OJ EPO 476.

[20] *Plant Genetic Systems* [1995] EPOR 357.

[21] *Howard Florey/H2 Relaxin* [1995] EPOR 541.

In support of the assertion that the interpretation of Article 27.2 should follow the EPO's approach to Article 53(a) EPC, it can be argued that this would allow the WTO to strike an appropriate balance between the competing goals of the liberalisation of trade and respect for IPRs on the one hand, with the need to afford a degree of discretion to WTO Members to pursue overriding policy goals by prohibiting, in extreme cases, the patentability of certain inventions on moral grounds.

(4) The 'WTO jurisprudence on exceptions' view

The fourth approach that has been suggested is that the interpretation of TRIPS Article 27.2 should follow the WTO jurisprudence on the interpretation of the 'general exceptions clauses' found in other WTO Agreements, such as Article XX of GATT and Article XIV of GATS.[22] GATT and GATS are multilateral agreements that set out the basic rules for international trade in goods and services respectively. Both agreements aim to eliminate barriers to trade through the establishment of a non-discriminatory trading system. WTO Members are obliged to respect, *inter alia*, the principles of national treatment (NT) and most-favoured-nation (MFN) treatment in relation to measures affecting trade in goods and services. Notwithstanding this commitment to trade liberalisation, the inclusion of general exceptions clauses in both instruments provides a degree of scope for Members wishing to justify the exclusion of certain products or services from their territory for a variety of domestic policy reasons. GATT Article XX, which reads as follows, can be compartmentalised into two sections; the enumerated exceptions and the introductory paragraph or 'chapeau':

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> (a) necessary to protect public morals;
> (b) necessary to protect human, animal or plant life or health;

GATS Article XIV(a) reflects the language of GATT Article XX(a).[23] Although there is as yet no case law dealing with the GATT Article XX(a) 'morality exception',[24] this provision has been relied upon by WTO Members to justify import bans on an array of products, including 'obscene and subversive literature', 'horror comics', alcoholic beverages, the Holy Quran, foodstuffs containing animal blood in their manufacturing and live swine and products of swine.[25] The GATT public morals exception could also conceivably be relied

[22] D Gervais *The TRIPS Agreement: Drafting History and Analysis*, 223.
[23] Article XIV(a) also provides an additional category of 'public order'. GATS Art. XIV(a), fn 5 states that: 'The public order exception may be invoked only where a genuine and sufficiently serious threat is posed to one of the fundamental interests of society'.
[24] For discussion see S Charnovitz 'The Moral Exception in Trade Policy' (1998) 38 Virginia Journal of International Law 689-745; M A Gonzalez 'Trade and Morality: Preserving "Public Morals" Without Sacrificing the Global Economy' (2006) 39 Vanderbilt Journal of Transnational Law 939-972; M Wu 'Free Trade and the Protection of Public Morals: An Analysis of the Newly Emerging Public Morals Clause Doctrine' (2008) 33 Yale Journal of International Law 215-251.
[25] P Van Den Bossche *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, 639–640.

upon to justify import bans on items such as 'blood diamonds' and products made by child labour.[26]

The interpretation of the term 'necessary' within the meaning of GATT Article XX(a) is likely to follow the two-tier 'necessity test' developed in the case law relating to Article XX(b).[27] This test has also been applied in the context of GATS. A clear illustration of how the test operates can be provided by the case of *US—Gambling* which is the only dispute to date that has involved the GATS Article XIV(a) 'public morals' clause.[28]

US—Gambling concerned complaints brought by Antigua against the United States for alleged GATS violations. Antigua asserted that a number of US federal and state laws which prohibit the remote supply of gambling and betting services, including Internet gambling, constituted a ban on the cross-border provision of Internet gambling services. The United States had argued that these measures were justified under Article XIV(a) because Internet gambling posed threats in relation to organised crime, money laundering and fraud; risks to children; and risks to health due to addiction to anonymous, 24-hour online gambling.

Under the first tier of the test, the Panel accepted that these concerns fell within the scope of the terms 'public morals' and 'public order' as set out in Article XIV(a).[29] Following prior GATT Article XX(b) jurisprudence,[30] the Panel then stated that in determining whether a measure is 'necessary' within the meaning of GATS Article XIV(a), it must 'weigh and balance' several factors, particularly the importance of the interests or values that the challenged measure is intended to protect,[31] the extent to which the challenged measure contributes to the realisation of the end pursued,[32] and the trade impact of the challenged measure.[33] The Panel found that the challenged US measures failed the 'necessity' test.[34] On

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[26] Ibid.

[27] P Van Den Bossche, ibid, 640.

[28] Panel Report, *US—Gambling*, WT/DS285/R (circulated 10 November 2004), as modified by the Appellate Body Report, WT/DS285/AB/R (adopted 20 April 2005). For commentary see J C Marwell 'Trade and Morality: The WTO Public Morals Exception after Gambling' (2006) 81 New York University Law Review 802-842; N F Diebold 'The Morals and Order Exceptions in WTO Law: Balancing the Toothless Tiger and the Undermining Mole' (2007) 11(1) Journal of International Economic Law 43-74.

[29] Panel Report, *US—Gambling*, para. 6.474.

[30] Appellate Body Report, *Korea—Measures Affecting Imports of Fresh, Chilled, and Frozen Beef (Korea—Various Measures on Beef)*, WT/DS161/AB/R, WT/DS169/AB/R (adopted 10 January 2001); Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products (EC—Asbestos)*, WT/DS135/AB/R (adopted 5 April 2001). See J C Marwell 'Trade and Morality: The WTO Public Morals Exception After *Gambling*' at 813, arguing that the "exact mechanics of this balancing test are somewhat opaque". For further critical commentary see D H Regan, 'The Meaning of 'Necessary in GATT Article XX and GATS Article XIV: The Myth of Cost-Benefit Balancing' (2007) 6(3) World Trade Review 347-369.

[31] Panel Report, *US—Gambling*, para. 6.477. With respect to this requirement, the Appellate Body has suggested that if the value or interest pursued is considered important it is more likely that the measure is 'necessary'. See Appellate Body Report, *Korea—Various Measures on Beef*, para. 162.

[32] Panel Report, *US—Gambling*, para. 6.477. In relation to this requirement, the Appellate Body has suggested that the greater the extent to which the measure contributes to the end pursued, the more likely that the measure is 'necessary'. See Appellate Body Report, *Korea—Various Measures on Beef*, para. 163.

[33] Panel Report, *US—Gambling*, para. 6.477. With regard to this requirement, the Appellate Body has said that if the measure has a relatively slight trade impact, the more likely the measure is 'necessary'. The Appellate Body has also indicated that whether a reasonably available WTO-consistent alternative measure exists must be taken into consideration in applying this requirement. See Appellate Body Report, *Korea—Various Measures on Beef*, paras. 163 and 166.

[34] Panel Report, *US—Gambling*, para. 6.535. This was due to the restrictive impact of the challenged measures and because the United States had failed to engage in consultations with Antigua in order to attempt to find reasonably available, less-trade restrictive alternatives to legislative prohibitions on Internet gambling.

appeal, the Appellate Body reversed this aspect of the Panel's decision, finding that the measures were 'necessary' within the meaning of GATS Article XIV(a).[35]

Under the second tier of the test, the Panel engaged in analysis under the chapeau of Article XIV, stating that in determining whether the application of the measures at issue constitutes 'arbitrary and unjustifiable discrimination' or a 'disguised restriction on trade':

> [T]he absence of consistency in this regard may lead to a conclusion that the measures in question are applied in a manner that constitutes 'arbitrary and unjustifiable discrimination' or a 'disguised restriction on trade'.[36]

When applied to the facts, the Panel in *US—Gambling* found that the United States had *not* been shown *not* to discriminate against foreign gambling service providers. This was because the United States had failed to prosecute certain domestic service providers and also because the Interstate Horseracing Act potentially authorised US companies to supply certain kinds of remote betting on horseracing in the United States whilst prohibiting foreign companies from engaging in the same activity.[37] On appeal, the Appellate Body upheld the Panel's finding that the US measures in question were discriminatory in their application.[38]

The two-tier necessity test developed and applied in relation to GATT Article XX(b) and GATS Article XIV(a) would offer two advantages as the framework for interpreting Article 27.2 of TRIPS. First, it would enable a flexible legal test for resolving disputes between WTO Members in areas involving sensitive moral judgements. Second, this methodology would also allow dispute settlement procedures to draw from a well-developed seam of jurisprudence regarding the interpretation of exceptions in WTO Agreements.

But which, if any, of the above four interpretive approaches would be adopted by a WTO panel or the Appellate Body in relation to the TRIPS morality exception? As the text and meaning of Article 27.2 remain shrouded in ambiguities, the rules relating to the interpretation of provisions in WTO Agreements assume paramount importance.

B: The interpretation of TRIPS Article 27.2

(1) General principles of interpretation

Although Article 3(2) of the WTO Dispute Settlement Understanding (DSU)[39] does not mention specifically the Vienna Convention on the Law of Treaties[40] (the 'Vienna Convention'), the WTO's Appellate Body has made it clear that both Articles 31 and 32 of the Vienna Convention have attained the status of rules of customary or general international law that panels and the Appellate Body have been directed, under Article 3(2) of the DSU, to apply in seeking to clarify the provisions of the General Agreement and the other 'covered

[35] Appellate Body Report, *US—Gambling*, para. 327. The Appellate Body rejected the Panel's 'necessity' analysis on the grounds that consultations with Antigua would not in themselves constitute a reasonably available alternative measure.

[36] Panel Report, *US—Gambling*, para. 6.584.

[37] Panel Report, *US—Gambling*, para. 6.607.

[38] Appellate Body Report, *US—Gambling*, paras. 348-351.

[39] Article 3(2) of the DSU provides that: 'The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements' (emphasis added).

[40] Vienna Convention on the Law of Treaties, open for signature 23 May 1969, 1155 United Nations, Treaty Series 331 (entered into force on 27 January 1980).

agreements' of the Marrakesh Agreement Establishing the World Trade Organization (the 'WTO Agreement').[41] Article 31(1) of the Vienna Convention provides that:

> A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

The principle of 'effective treaty interpretation', which can be seen as the corollary of the rule that a treaty be interpreted in 'good faith', requires an interpreter to give effect to all the terms of a treaty and to avoid a reading of a provision that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.[42] The Panel in *US—Gambling* also observed that: 'the principle of good faith in the process of interpretation underlies the concept that interpretation should not lead to a result which is manifestly absurd or unreasonable'.[43]

Article 31(3) of the Vienna Convention further states that in addition to the context, account should be taken of any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions, as well as of any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation. Article 32 of the Vienna Convention adds that recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31 leaves the meaning ambiguous or obscure or leads to a result which is manifestly absurd or unreasonable.

There is no formal rule of *stare decisis* in WTO dispute settlement proceedings. The Appellate Body has nevertheless indicated that previous decisions 'create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute'.[44] Furthermore, although the TRIPS Agreement occupies a relatively self-contained, *sui generis* status in the WTO Agreement, it is nevertheless an integral part of the WTO system. The WTO panels or the Appellate Body could therefore refer to other WTO Agreements and their interpretation in prior decisions when interpreting Article 27.2 of TRIPS.[45]

In WTO dispute settlement proceedings, 'exception clauses' are invoked as a defence by a respondent WTO Member State after a complaining state has established a *prima facie* case that the respondent has violated a trade obligation.[46] The Appellate Body has emphasised that exceptions are not necessarily construed in a deliberately narrow fashion so that a derogation does not erode core obligations, but rather by a 'balanced' interpretation of a particular

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[41] Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline* (*'US—Gasoline'*), WT/DS2/AB/R (adopted 20 May 1996), 16; Appellate Body Report, *Japan—Taxes on Alcoholic Beverages* (*Japan—Alcoholic Beverages II*), WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (adopted 1 November 1996), 9.

[42] Appellate Body Report, *US—Gasoline*, 21.

[43] Panel Report, *US—Gambling* para. 6.49.

[44] Appellate Body Report, *Japan — Alcoholic Beverages II*, 13.

[45] Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products—Complaint by the United States* (*India—Patents (US)*), WT/DS5O/R (adopted 5 September 1997), para. 7.19. See Olivier Cattaneo 'The Interpretation of the TRIPS Agreement: Considerations for the WTO Panels and the Appellate Body' (2000) 3 The Journal of World Intellectual Property 627-681 at 668.

[46] Appellate Body Report, *United States—Measures Affecting Imports of Woven Woollen Shirts and Blouses from India (US—Wool Shirts and Blouses)*, WT/DS33/AB/R (adopted 23 May 1997) 15-16; Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones) (EC—Hormones (Canada))*, WT/DS26/AB/R, WT/DS48/AB/R, (adopted 13 February 1998), paras. 98 and 104.

provision, given its text, context, object and purpose, and taking into account the often conflicting goals of the liberalisation of trade and the promotion of other societal values.[47]

(2) Text

The concepts of '*ordre public*' and 'morality' found in Article 27.2 are not defined in the TRIPS Agreement. It is highly likely, however, that the meaning ascribed to the terms 'public morals' and 'public order' in Article XIV(a) of GATS and interpreted by the Panel in *US—Gambling* would be of relevance when interpreting Article 27.2 of TRIPS. The Panel found that 'public morals' and 'public order':

> [C]an vary in time and space, depending upon a range of factors, including prevailing social, cultural, ethical and religious values.[48]

According to the Panel:

> Members should be given some scope to define and apply for themselves the concepts of 'public morals' and 'public order' in their respective territories, according to their own systems of scales and values.[49]

The Panel referred to the *Shorter Oxford English Dictionary* definition of the term 'morals' ('habits of life with regard to right and wrong conduct'), and held that the term 'public morals' denotes:

> [S]tandards of right and wrong conduct maintained by or on behalf of a community or nation.[50]

As for the term 'public order', the Panel in *US—Gambling* concluded that the dictionary definition of the term 'order', read together with footnote 5 of GATS Article XIV(a), suggests that 'public order' refers to:

> [T]he preservation of the fundamental interests of a society, as reflected in public policy and law. These fundamental interests can relate, *inter alia*, to standards of law, security and morality.[51]

The Appellate Body did not disturb the Panel's interpretation of the phrases 'public morals' and 'public order'. Even though interpreting the term 'public order' in the same way as the term '*ordre public*'[52] would render the drafters intention in using the French term in Article 27.2 superfluous, there is nevertheless likely to be a degree of overlap between the meaning ascribed to these terms, as they seek to protect largely similar interests.

The definition of the term 'commercial exploitation' may be influenced by the meaning given to the phrase 'exploitation of the patent' found in Article 30 of TRIPS and understood

[47] Appellate Body Report, *US—Gasoline*, 16-17.
[48] Panel Report, *US—Gambling*, para. 6.461.
[49] Ibid.
[50] Ibid, para 6.465.
[51] Ibid, para. 6.467.
[52] The EPO's interpretation of '*ordre public*', which it has stated as encompassing the protection of public security and the physical integrity of individuals as part of society, as well as the protection of the environment, may be influential in constructing this term in the context of TRIPS. *Plant Genetic Systems* [1995] EPOR 357 at para. 5.

by the Panel in *Canada—Pharmaceuticals* as relating to the 'commercial activity' by which patent owners 'extract economic value' from their invention.[53]

Unfortunately, the clarification of these individual terms casts fairly little light on the overarching question of which, if any, of the four views on the interpretation of Article 27.2, outlined above, would be adopted in WTO dispute settlement proceedings. Nevertheless, a critique of the robustness of the 'EPO morality jurisprudence view' can be ventured simply on the basis of a comparison of the text of Article 27.2 of TRIPS with Article 53(a) EPC 1973. Article 53(a) EPC 1973 states that European patents shall not be granted in respect of:

> [I]nventions the *publication or exploitation* of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States' (emphasis added).

Article 27.2 of TRIPS, however, only authorises WTO Member States to exclude from patentability: '…inventions, *the prevention within their territory of the commercial exploitation of which is necessary* to protect *ordre public* or morality' (emphasis added). There are therefore two reasons for arguing that Article 27.2 should be interpreted in a way that is distinct to and narrower than Article 53(a) EPC 1973. First, Article 27.2 establishes a link between the denial of patentability and the necessity of the *prevention* of commercial exploitation, whereas the scope for excluding inventions under Article 53(a) EPC 1973 is broader; set instead to an expansive, 'free-standing' criterion that is not directly connected to the prevention of commercial exploitation. Second, the view that TRIPS Article 27.2 provides a more restrictive rule than Article 53(a) EPC is supported by an analysis of the drafting history of Article 27.2,[54] which reveals that negotiators first presented a text in 1990 (W/76) that stated in Article 4:

> The following [shall] [may] be excluded from patentability:
> 4.1 Inventions, [the publication or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [public health,] [or the basic principle of human dignity] [or human values].[55]

This was narrowed in the following 'Brussels Draft', which included an exception that would allow parties to exclude from patentability:

> [I]nventions, the prevention within their territory *of the publication* or any exploitation of which is necessary; to protect public morality or order, including to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement; or to protect human, animal or plant life or health (emphasis added).[56]

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[53] Panel Report, *Canada—Pharmaceuticals*, para 7.54. For discussion on whether the not-for profit manufacture and distribution of a product would amount to 'commercial exploitation', see C Henckels 'The Ostensible "Flexibilities" in TRIPS: Can Essential Pharmaceuticals Be Excluded from Patentability in Public Health Crises' at 347–348; E B Rodrigues Jr. and B Murphy 'Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines' (2006) 16 Albany Law Journal of Science and Technology 423-456.

[54] It is noted that analysis under Article 31 of the Vienna Convention must be completed before recourse may be had to the preparatory works of a treaty under Article 32.

[55] D Gervais, *The TRIPS Agreement: Drafting History and Analysi*s, 219.

[56] Ibid, 218.

The fact that the parties chose to delete the reference to 'publication' in the final draft of the TRIPS Agreement strengthens the view that Article 27.2 requires consideration of the prevention of the commercial exploitation of the invention for reasons of *ordre public* or morality, rather than of the consequences of the grant and publication of the patent.[57] The textual differences between Article 27.2 of TRIPS and Article 53(a) EPC therefore suggest that the EPO's 'morality jurisprudence' would be, at best, of very limited persuasive effect for a WTO panel or the Appellate Body. The remainder of this section will therefore only assess the remaining three views on the interpretation of Article 27.2, moving from textual analysis to consideration of its context, object and purpose.

(3) Context and object and purpose

There are several provisions in the TRIPS Agreement that would be of importance to the interpretation of Article 27.2 The Preamble and Article 1.1 of TRIPS demonstrate that the basic purpose of the Agreement is to reduce distortions and barriers to international trade by laying down minimum requirements for the protection and enforcement of intellectual property rights. Other provisions of the TRIPS Agreement may also be of relevance in elucidating the meaning of Article 27.2. Articles 7 and 8.1 of TRIPS can be viewed as 'balancing provisions' that enshrine the goal of achieving equilibrium between competing policy objectives. Article 7 provides that:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8.1 states that:

> Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

In *Canada—Pharmaceuticals*, Canada asserted that the text of Article 7 declares that one of the key goals of the TRIPS Agreement is to strike a balance between the intellectual property rights created by the Agreement and other important socio-economic policies of WTO Member governments.[58] Article 8.1 was said to elaborate further upon the socio-economic policies in question. It could be argued that these purposes call for an interpretation of TRIPS that would give WTO Members a reasonable degree of discretion to exclude inventions from patentability on grounds of *ordre public* or morality so that the obligation to make patents available in all fields of technology could be balanced against other important national policies. This assertion would, however, seem to be at odds with the Panel's more nuanced interpretation of the influence of Articles 7 and 8.1 in *Canada—Pharmaceuticals*, where it was held that the exact scope of the provision under scrutiny (in that particular case Article 30) would:

[57] R Rajnish Kumar 'Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations Under the TRIPS Agreement and Options for India' (2008) 8 Chicago-Kent Journal of Intellectual Property 41–84 at 66.

[58] Panel Report, *Canada—Patent Protection of Pharmaceutical Products (Canada—Pharmaceutical Patents)*, WT/DS114/R (adopted 7 April 2000), para. 7.24.

> [D]epend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.[59]

On the basis of the Panel's opinion in *Canada—Pharmaceuticals*, Articles 7 and 8.1 would be of relevance when construing the wording of Article 27.2, but they would by no means act as 'trump cards' that would automatically lead to a flexible approach to the interpretation of the TRIPS morality exception.

Two other provisions within TRIPS must also be considered in order to understand the scope and contents of Article 27.2. First, Article 30 provides that:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The Panel in *Canada—Pharmaceuticals* held that an exception to patent rights under Article 30 must meet three cumulative requirements: first, the exception must be 'limited'; second, it must not 'unreasonably conflict with a normal exploitation of the patent'; and third, it must not 'unreasonably prejudice the legitimate interests of the patent owner; taking account of the legitimate interests of third parties. It is important to point out that Article 30 relates to 'limited exceptions to the exclusive rights conferred by a patent', and therefore deals with restrictions on exclusive rights conferred by patents that have already been granted, and not the issue of patentability *per se* under Article 27.1.[60] Article 30 may, nevertheless, still inform the interpretation of Article 27.2, pointing to an approach whereby the 'reasonableness' of measures excluding inventions from patentability would be scrutinised.

Second, and more importantly, it is clear that the object and purpose of Article 27.2 is to provide a limited exception to the obligation on WTO Members set out in Article 27.1. Article 27.2 must therefore be read in close conjunction with Article 27.1, with the text of the exception being informed by the wording of the rule to which it provides a limited derogation. Crucially, Article 27.1 states that 'patents shall be available and patent rights enjoyable without *discrimination* as to the….field of technology' (emphasis added). In *Canada—Pharmaceuticals*, the Panel considered whether the Canadian regulatory review provision discriminated as to the field of technology, namely pharmaceuticals, interpreting the term in the following way:

> The ordinary meaning of the word 'discriminate'…certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the *unjustified* imposition of differentially disadvantageous treatment. As noted above, de facto discrimination is a general term describing the legal conclusion that an ostensibly neutral measure transgresses a non-discrimination norm because its actual effect is to impose differentially disadvantageous consequences on certain parties, and because those measures are found to be *wrong or unjustifiable*.[61]

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[59] Ibid, para. 7.26.

[60] R Rajnish Kumar 'Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations Under the TRIPS Agreement and Options for India' at 65.

[61] Panel Report, *Canada—Pharmaceutical Patents*, para. 7.94.

The meaning of Article 27.2 must therefore be shaped by the principle that the measures excluding an invention on the grounds of *ordre public* or morality must not be 'discriminatory', in the sense of being 'unjustified', in nature.

(4) Interpreting Article 27.2: The necessity of a ban on commercial exploitation

How would the above discussion assist a panel or the Appellate Body in the interpretation of Article 27.2, particularly in relation to the three remaining academic views on the provisions scope and contents? When read in conjunction with Article 27.1 and Article 30, an exclusion of patentability on the grounds of *ordre public* or morality would only seem to be legitimate if it were 'reasonable', 'justifiable' and 'non-discriminatory'. The specific wording used in Article 27.2 must be analysed and interpreted according to this framework of guiding principles. In addition, the drafting history of Article 27.2 suggests strongly that the common intention of the parties was to establish a central role for the prevention of the commercial exploitation of the invention in order to justify exclusions from patentability.

Upon consideration of these textual and contextual factors, it is suggested that the most reasonable and appropriate interpretation of Article 27.2 would be to require WTO Members to first prohibit the sale and distribution of an invention before excluding it from patentability on the grounds of *ordre public* or morality. It is extremely difficult to see how a WTO Member could argue convincingly that the prevention of the commercial exploitation of an invention in its territory was 'necessary' if it in fact permitted the commercial exploitation of that invention.[62] Furthermore, options for interpreting Article 27.2 that would tolerate a mismatch between the standards of *ordre public* or morality expressed within a WTO Member's patent laws and those expressed within the Member's domestic regulations would contravene the principles of 'reasonableness', 'justifiability' and 'non-discrimination' that must be brought to bear on the construction of the provision. Finally, there are also strong policy reasons in support of the 'necessity of a ban on commercial exploitation' view. To permit Article 27.2 to be utilised in more flexible ways could open the floodgates to protectionism and free-riding. This would undermine the fundamental object and purpose of Article 27.1, and indeed of the entire TRIPS Agreement.

(5) Counter-arguments

Three counter-arguments in favour of alternative interpretations of Article 27.2 can be raised:

(a) Acquiescence

The first argument flows from the principle of 'acquiescence', which has been defined by a commentator in the following way: '[i]f a party has made plain its understanding of the meaning of a provision, and it later applies it in that sense without objection, other parties may not be able to insist on a different interpretation. Article 31:3(b) [of the Vienna Convention] might also apply'.[63] The doctrine of acquiescence was accepted by the Panel in *US—Gambling* as being a valid guide to the interpretation of WTO Agreements.[64] The practice of WTO Members in relation to the exclusion of certain inventions from

[62] K C Cheney 'Patentability of Stem Cell Research under TRIPS: Can Morality-Based Exclusions be Better Defined by Emerging Customary International Law?' (2007) 29 Loyola of Los Angeles International and Comparative Law Review' 503–536 at 532.
[63] A Aust *Modern Treaty Law and Practice*, (Cambridge University Press 2000) 200.
[64] Panel Report, *US—Gambling*, para. 6.114

patentability on moral grounds in the years after the TRIPS Agreement came into force (i.e. after 1 January 1995) could therefore inform the interpretation of Article 27.2.

The sole case of potential relevance is a 1999 decision of the United States Patent and Trademark Office (USPTO), in which a patent application made by Stuart Newman and Jeremy Rifkin (Newman-Rifkin I) for combining human and nonhuman embryonic cells to develop a 'humanoid' chimera was rejected, even though the sale and distribution of the invention was not prohibited in the United States. A media advisory issued by the USPTO stated that amongst other reasons for the rejection of the patent:

> [I]nventions directed to human/ non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.[65]

As far as can be discerned, no WTO Members registered any objection to this decision or suggested that this approach might contravene Article 27.2 of TRIPS. It is, however, highly doubtful that the USPTO ruling in the Newman-Rifkin I application would be deemed to constitute 'subsequent practice' that would determine the interpretation of Article 27.2 of TRIPS. In *Japan—Alcoholic Beverages II* the Appellate Body referred to 'practice' within the meaning of Article 31(3)(b) of the Vienna Convention as:

> [A] 'concordant, common and consistent' sequence of acts or pronouncements which is sufficient to establish a discernible pattern implying the agreement of the parties [to a treaty] regarding its interpretation.[66]

Under this legal test, a single ruling by one WTO Member indicating a decision to exclude an invention from patentability whilst permitting the sale and distribution of the invention within its territory would not establish 'practice' indicating agreement amongst WTO Members on a particular interpretation of the TRIPS morality exception.

(b) The distinction between legality and morality in TRIPS

A second criticism of the 'necessity of a ban on commercial exploitation' view would be to restate the observation that Article 27.2 establishes quite clearly that an invention should not be excluded 'merely' on the grounds that it is prohibited by law or regulation. This suggests that the concepts of illegality and immorality ought to be regarded as separate and distinct within TRIPS. Arguably, if the illegal nature of a given invention is not determinative for the purposes of applying the morality exclusion, then neither should it be a necessary condition for excluding the patentability of inventions. This argument, however, breaks down under closer inspection. The sale and distribution of certain inventions might be prohibited by laws or regulations that reflect concerns of a more technical, as opposed to moral, nature.[67] The final phrase of Article 27.2 simply reflects the idea that patentability should not be denied for this narrow category of inventions. Thus, even though it is beyond doubt that the exclusion of the exploitation of the invention is not a *sufficient* condition for exclusion of patentability

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[65] USPTO 'Facts on Patenting Life Forms having a Relationship to Humans' (1998) Media Advisory No. 98-6. Available at: <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>. See S Rabin 'The Human Use of Humanoid Beings: Chimeras and Patent Law' (2006) 24(5) Nature Biotechnology 517–519.

[66] Appellate Body Report, *Japan—Alcoholic Beverages II*, 11.

[67] This is in line with Article 4quater of the Paris Convention for the Protection of Industrial Property (1883, as revised), which states that: '[t]he grant of a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law'.

under Article 27.2, it does not follow logically that a ban on commercial exploitation can not be a *necessary* condition.

(c) The appropriateness of a two-tier 'necessity' test

A third counter-argument could be to suggest that a panel or the Appellate Body would not approach the interpretation of Article 27.2 by means of a simplistic, binary test to examine only whether the commercial exploitation of the invention had been prohibited within a WTO Member's territory before a patent was denied on moral grounds. Instead, it has been suggested that the term 'necessary' in Article 27.2 would trigger a 'reading in' of the two-tier 'necessity test' in accordance with WTO case law under GATT Article XX(b) and GATS Article XIV(a), perhaps using Article 30 of TRIPS as a 'substitute chapeau'.[68] At first glance this opinion seems reasonable, given the similarity between the structure and wording of the relevant exceptions in GATT, GATS and TRIPS. Furthermore, it may also be desirable from a policy perspective to permit a more fine-grained and flexible legal test for assessing the various measures and factual backgrounds that may prompt WTO Members to exclude inventions from patentability on the grounds of *ordre public* or morality. There are some practical problems with this view.

If a WTO Member believes that a class of inventions poses a genuine threat to *ordre public* or morality, and if appropriate regulatory measures are reasonably available for the Member to prevent the commercial exploitation of the inventions but these measures are not adopted, then the denial of patent protection in such circumstances could never be deemed to be 'necessary'. As Correa observes:

> Generally, patent offices have no power to prevent the commercialization of a product. The refusal of protection, on the other hand, does not necessarily lead to the exclusion of commercialization.[69]

The exclusion from patentability could therefore not make a significant contribution to the aim of preventing the sale and distribution of the inventions within the WTO Member's territory. A two-tier 'necessity' test would therefore be a wholly redundant and meaningless exercise in the context of Article 27.2, as the outcome of the test would be a foregone conclusion if the commercialisation of the invention had not also been prohibited.[70]

The term 'necessary' in Article 27.2 must therefore refer to the necessity of preventing the commercial exploitation of the invention, rather than the necessity of excluding the invention from patentability. Whilst this may seem to be a subtle distinction, the implication is that any weighing and balancing of the necessity of the prevention of the sale and distribution of the invention would need to be conducted under Article XX of GATT or relevant provisions in other WTO Agreements.[71] This reinforces the view that Article 27.2 would only countenance exclusions from patentability if the WTO Member has first banned the commercial exploitation of the invention on the grounds of *ordre public* or morality.

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[68] D Gervais *The TRIPS Agreement: Drafting History and Analysis*, 223. Also discussed in C Henckels 'The Ostensible Flexibilities in TRIPS: Can Essential Pharmaceuticals Be Excluded from Patentability in Public Health Crises?' at 349-350.

[69] C M Correa and A A Yusuf *Intellectual Property and International Trade: The TRIPS Agreement*, (Kluwer Law International 1998) 193.

[70] R Rajnish Kumar 'Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations Under the TRIPS Agreement and Options for India' 68.

[71] For example, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the 'SPS Agreement') and the Agreement on Technical Barriers to Trade (the 'TBT Agreement').

(6) A legal test for Article 27.2 of TRIPS

Analysis of the text, context and object and purpose of Article 27.2 of TRIPS suggests that it should be interpreted by means of a binary test that would focus on the question of whether or not a ban on the sale or distribution of the invention is in force within the territory of the WTO Member. This kind of binary approach was adopted in a slightly different context by the European Court of Justice (ECJ) in *Conegate v Customs and Excise Commissioners*.[72] This case concerned the seizure of life-size, inflatable dolls and other materials by United Kingdom customs officers on the grounds that the items were 'indecent and obscene' within the meaning of English customs legislation.[73] The ECJ found the seizure to be unjustified because the restrictions within the UK placed on the domestic goods did not amount to a prohibition on manufacture or sale. When assessing the consistency of the domestic measures with the import ban, the ECJ held that:

> [I]t must be at least possible to conclude from the applicable rules, taken as a whole, that their purpose is, in substance, to prohibit the manufacture and marketing of those products.[74]

The following sections suggest how a *Conegate*-type test for assessing domestic regulations might be applied in relation to the moral restrictions on the patentability of hESC-related inventions in Europe.

(a) Article 6.2(c) of the EU Biotechnology Directive

Article 6.2(c) of the EU Biotechnology Directive, which prohibits the patenting of 'uses of human embryos for industrial or commercial purposes' in all EU Member States, would fail to meet the requisite standard.[75] This is because it is not possible to conclude from an examination of the applicable rules regarding 'uses of human embryos for industrial or commercial purposes' across EU Member States, that taken as a whole, these rules prohibit the manufacture and marketing of such goods throughout the EU.[76]

Article 6.2(c) of the EU Biotechnology Directive has also been transposed into the domestic patent laws of all EU Member States. Under the same approach, the domestic patent laws of the individual EU Member States that have *not* banned the sale and distribution of goods relating to the use of human embryos for industrial or commercial purposes would also fail a *Conegate*-type test. By the same token, the individual EU Member States that do actually maintain effective prohibitions on the sale and distribution of 'uses of human embryos for industrial or commercial purposes' (e.g. Austria[77]) would be entitled to exclude related inventions from patentability under Article 27.2 of TRIPS.

(b) Morality and the EPC framework

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[72] *Conegate v Customs and Excise Commissioners* (Case 121/85) [1986] ECR 1007, [1986] 1 CMLR 739, European Court of Justice.
[73] See E Berry, S Hargreaves and E Deards *European Union Law*, 2nd edn (Oxford University Press 2007) 175.
[74] *Conegate v Customs and Excise Commissioners*, 17.
[75] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (1998) OJ L213/13.
[76] See generally A Elstner et al. 'The Changing Landscape of European and International Regulation on Embryonic Stem Cell Research'.
[77] Austrian Reproductive Medicine Act (1992).

The centralised patent application system under the EPC presents further questions.[78] Rule 28(c) transposes Article 6.2(c) of the Biotechnology Directive into the EPC framework, and thus imposes a blanket ban on the issuance of patents relating to 'industrial or commercial uses of the human embryo' by the EPO, regardless of whether the marketing and manufacture is authorised in the individual EPC states selected by the patent applicant. It is suggested that the blanket rule of Rule 28(c) would likely be held to be unacceptable. Alternative institutional arrangements that allowed patents to be granted for the EPC countries that permit the sale and distribution of inventions relating to 'uses of the human embryo for industrial or commercial purposes', whilst preventing the granting of patents for any EPC states that have effective bans on the commercial exploitation of these inventions would, however, be permitted under a *Conegate*-type approach to Article 27.2.

(c) Prohibitions on the preliminary steps of manufacture

Additional complexities are raised by the scenario whereby bans are in place on the preliminary steps of the manufacture of an invention, but where the sale and distribution of the completed article is lawful within a WTO Member's territory. In Germany, for example, the Stem Cell Act prohibits the derivation of hESC within Germany, but licences to import hESC lines created outside Germany can be applied for on a case-by-case basis. Only hESC lines that were created before 1 May 2007 and were derived from surplus embryos left over from in vitro fertilisation procedures can be imported.[79] Would the prohibition only on the derivation of hESC lines within Germany permit a general exclusion on the patentability of all aspects and applications of hESC-technology?[80] There are two possible approaches.

First, a WTO panel or the Appellate Body could take a deferential stance towards the Member's political decision to ban the preliminary steps of manufacturing the invention within its territory. Under this approach, the WTO Member would be entitled to prohibit patent applications that pertain directly to the 'immoral' preliminary steps *and also* to applications pertaining to the completed invention and its use, even though the completed article can lawfully be sold and distributed within that Member's territory. Alternatively, the stricter view would emphasise the desirability of removing trade distortions and therefore require a WTO Member to prohibit not only the preliminary steps of making the invention but also the sale and distribution of the completed article before it could justify the exclusion of the entire class of technology from patentability.

It is suggested that the second, stricter option is to be preferred. Requiring WTO Members to grant patents for inventions that can lawfully be sold and distributed within their territory following the completion of the preliminary steps of their manufacture would in no way alter or compromise the legal prohibition on conducting those early steps within the Member's territory. The stricter approach would also prevent the problem of WTO Members gaining an unfair competitive advantage by allowing domestic researchers to free-ride on the efforts and investment of foreign inventors.

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[78] For an overview of the centralised system for the grant of 'European patents' under the EPC framework, see L Bently and B Sherman, *Intellectual Property Law*, 3rd edn (Oxford University Press 2009) 341–342.

[79] A Elstner et al. 'The Changing Landscape of European and International Regulation on Embryonic Stem Cell Research', 104–105. Italy and the Republic of Ireland have also implemented similar regimes. 'UCC to Allow Controversial Stem Cell Research' (2008) Centre for Ageing Research and Development in Ireland. Available at: <http://www.cardi.ie/news/ucctoallowcontroversialstemcellresearch>.

[80] In December 2006, the German Federal Patent Court revoked a patent issued to neurobiologist Oliver Brüstle on a method of generating neural precursor cells on the grounds that the cells involved the destruction of human embryos and therefore breached guidelines issued by the German Patent Office. See A Abbott 'Stem Cell Technique "Contrary to Public Order"' (2006) 444 Nature 799.

(7) TRIPS Article 27.3(b): The exclusion of 'animals' from patentability

On a final note, Article 27.3(b) of TRIPS provides that Members may exclude from patentability:

> [P]lants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

In contrast to Article 27.2, Article 27.3(b) does not establish any requirement to prohibit the sale and distribution of inventions that fall within its scope before excluding them from patentability. If the term 'animals' could be construed broadly to encompass *homo sapiens*, then WTO Members would be permitted to deny patents for inventions relating to 'humans' or 'essentially biological processes' for their production without the need to also prevent the commercial exploitation of such inventions. On this basis, it could be argued that patents claiming human totipotent cells, which have the potential to develop into an entire human body, could be excluded from patentability on the grounds that they contain claims directed towards an 'animal in development'.[81] Embryonic, multipotent and pluripotent cells, which do not have the potential to develop into an entire human body, would fall outside the scope of this rule and could not be excluded from patentability under Article 27.3(b) of TRIPS.

Conclusion

Notions of 'morality' may differ greatly amongst WTO Members. What is acceptable in one country may be seen as offensive or injurious to prevailing moral standards in another. This chapter has asserted that although a degree of scope is afforded to WTO Members to exclude goods and services from their territory in order to protect 'public morals' by virtue of GATT Article XX and GATS Article XIV, Article 27.2 of the TRIPS Agreement is likely to be interpreted and applied in a more restrictive fashion.

The chapter has argued that as the text of Article 27.2 must be analysed closely and read in conjunction with Article 27.1 and Article 30, the most reasonable understanding of Article 27.2 is that put forward by Van Den Bossche and others.[82] Under this interpretation, a WTO Member must first prevent the commercial exploitation of the invention within its territory in order to legitimately exclude the invention from patentability. Failure to do so will mean that it cannot rely on Article 27.2 to justify deviating from its core obligation under Article 27.1 to make patents available without 'discrimination' as to the field of technology. Under this understanding of Article 27.2, the bulk of the measures restricting the patentability of hESC technology in Europe would not be TRIPS-compatible. Even so, it may be possible to exclude totipotent cells from patentability under Article 27.3(b) of TRIPS without any need for a WTO Member to prohibit the sale and distribution of these cells within its territory.

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[81] See UK Intellectual Property Office, Practice Notice 'Inventions Involving Human Embryonic Stem Cells' (3 February 2009). The Practice Notice states that: 'Human totipotent cells have the potential to develop into an entire human body. In view of this potential, such cells are not patentable because the human body at the various stages of its formation and development is excluded from patentability'. Available at: <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm>. For a forceful critique of this approach in the Canadian context, see G R Hagen 'Potency, Patenting and Preformation: The Patentability of Totipotent Cells in Canada' (2008) 5(3) *SCRIPTed* 515–552.

[82] P Van Den Bossche *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, 785.